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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

OREXO AB, *Plaintiff,* v. ACTAVIS LABORATORIES FL, INC. *Defendant*.	Honorable Peter G. Sheridan, U.S.D.J. Civil Action No. 3:15-cv-00826 (PGS/DEA) **ANSWER, AFFIRMATIVE DEFENSES, COUNTERCLAIMS, AND JURY DEMAND OF DEFENDANT ACTAVIS LABORATORIES FL, INC.** *Electronically Filed*

Defendant Actavis Laboratories FL, Inc. ("Actavis FL" or "Defendant") by and through the undersigned attorneys, answers the Complaint of Plaintiff Orexo AB ("Orexo" or "Plaintiff") as follows. This pleading is based upon Actavis FL's knowledge as to its own activities, and upon information and belief as to the activities of others.

1. Plaintiff Orexo AB ("Plaintiff or "Orexo"), for its Complaint against Actavis Laboratories FL, Inc. ("Actavis FL"), Andrx Corporation ("Andrx"), Actavis, Inc., and Actavis Pharma, Inc. ("Actavis Pharma") (collectively, "Actavis" or "Defendants"), alleges as follows:

Answer: Paragraph 1 is an introduction to which no response is required. To the extent a response is required, Actavis FL admits that Orexo filed this Complaint against the listed Defendants. Actavis FL notes that Andrx Corporation, Actavis, Inc., and Actavis Pharma, Inc. were dismissed from this case by stipulation on March 16, 2015. (Dkt. 18). Actavis FL denies the remaining allegations of Paragraph 1, and expressly denies that Plaintiff is entitled to any relief.

NATURE OF THE ACTION

2. This is an action for patent infringement arising under the Patent and Food and Drug laws of the United States, Titles 35 and 21, United States Code.

Answer: Actavis FL admits that the Complaint purports to bring an action for infringement and that the action arises under Titles 35 and 21 of the United States Code. Actavis FL denies the remaining allegations of Paragraph 2, and expressly denies that Plaintiff is entitled to any relief.

3. On information and belief, Defendants have been and are engaging in activities directed toward infringement of United States Patent No. 6,759,059 ("the '059 patent"), United States Patent No. 6,761,910 ("the '910 patent"), and United States Patent No. 7,910,132 ("the '132 patent"), by, *inter alia*, submitting an abbreviated new drug application designated ANDA No. 207338 seeking FDA approval to manufacture and commercially market their proposed products called "Fentanyl Sublingual tablets, CII" (hereinafter referred to as "Actavis's ANDA Products") containing the active ingredient Fentanyl Citrate.

Answer: Actavis FL admits that it submitted ANDA No. 207338 seeking FDA approval to manufacture and commercially market a product called "Fentanyl Sublingual tablets, CII" and containing the active ingredient Fentanyl Citrate. Actavis FL denies the remaining allegations of Paragraph 3.

4. In a letter dated December 23, 2014, titled "Notification of Certifications for U.S. Patent Nos. 6,759,059; 6,761,910 and 7,910,132 Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act" (hereinafter referred to as the "December 23 Notice Letter"), Actavis FL notified Orexo that it had filed ANDA No. 207338 and that it intends to manufacture and commercially market Actavis's ANDA Products (a generic version of Abstral®) before

expiration of the '059, '910, and '132 patents.

Answer: Actavis FL admits the allegations of Paragraph 4.

THE PARTIES

5. Plaintiff Orexo is a company organized and existing under the laws of Sweden, having its principal place of business at Uppsala, Sweden. Orexo was a corporate name change from Diabact AB.

Answer: Actavis FL admits the allegations of Paragraph 5, on information and belief.

6. On information and belief, defendant Actavis FL is a corporation organized and existing under the laws of the State of Florida, having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054. On information and belief, Actavis FL is a wholly-owned subsidiary of Andrx.

Answer: Actavis FL admits that it is a corporation organized and existing under the laws of the State of Florida. Actavis FL denies that its principal place of business is at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054. Actavis FL's principal place of business is 4955 Orange Drive, Davie, FL 33314. Actavis FL admits that it is a wholly-owned subsidiary of Andrx Corporation, which is a wholly-owned subsidiary of Actavis, Inc. Except as expressly admitted, Actavis FL denies the remaining allegations in Paragraph 6.

7. On information and belief, Actavis FL is in the business of manufacturing, marketing, importing, preparing, and selling generic pharmaceutical products that it distributes in the State of New Jersey and throughout the United States.

Answer: Actavis FL admits that it manufactures and sells generic pharmaceutical products in the United States. Actavis FL denies the remaining allegations in Paragraph 7.

8. On information and belief, defendant Andrx is a corporation organized under the laws of the State of Delaware, having designated its registered agent as The Corporation Trust Company, Corporation Trust Center, 1209 Orange St., Wilmington, DE 19801. On information and belief, Andrx is a wholly-owned subsidiary of Actavis, Inc.

Answer: Paragraph 8 is directed to an entity that is no longer a party to this

litigation (Dkt. 18), and therefore no answer is necessary.

9. On information and belief, defendant Actavis Pharma is a corporation organized and existing under the laws of the State of Delaware, having a place of business at Morris Corporate Center III, 400 Interspace Parkway, Parsippany, NJ 07054. On information and belief, Actavis Pharma is a wholly-owned subsidiary of Actavis, Inc.

Answer: Paragraph 9 is directed to an entity that is no longer a party to this litigation (Dkt. 18), and therefore no answer is necessary.

10. On information and belief, Actavis Pharma is in the business of, among other things, marketing and distributing pharmaceutical products in the State of New Jersey and throughout the United States, including those that are manufactured by Actavis FL.

Answer: Paragraph 10 is directed to an entity that is no longer a party to this litigation (Dkt. 18), and therefore no answer is necessary.

11. On information and belief, defendant Actavis, Inc. is a corporation organized and existing under the laws of the State of Nevada, having a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054. On information and belief, Actavis, Inc. holds a current and valid "Wholesale Drug & Medical Device" registration in New Jersey (Registration No. 5003854).

Answer: Paragraph 11 is directed to an entity that is no longer a party to this litigation (Dkt. 18), and therefore no answer is necessary.

12. On information and belief, Actavis, Inc. is in the business of, among other things, marketing and distributing pharmaceutical products in the State of New Jersey and throughout the United States, including those that are manufactured by Actavis FL.

Answer: Paragraph 12 is directed to an entity that is no longer a party to this litigation (Dkt. 18), and therefore no answer is necessary.

JURISDICTION AND VENUE

13. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202, and venue is proper pursuant to 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

Answer: Paragraph 13 contains conclusions of law for which no response is required. To the extent a response is required, Actavis FL does not contest subject matter

jurisdiction or venue in this judicial district for the limited purpose of this action only.

14. This Court has personal jurisdiction over Defendants because they have purposefully availed themselves of the privilege of selling their pharmaceutical products in the State of New Jersey and, therefore, can reasonably expect to be subject to jurisdiction in the New Jersey courts. Among other things, on information and belief, Defendants conduct marketing and sales activities in the State of New Jersey, including, but not limited to, the distribution, marketing, and sales of pharmaceutical products to New Jersey residents that are continuous and systematic.

Answer: Paragraph 14 contains conclusions of law for which no response is required. To the extent a response is required, and solely to conserve the resources of the parties and the Court, Actavis FL does not contest personal jurisdiction in this judicial district for the limited purpose of this action only. Actavis FL denies the remaining allegations of Paragraph 14.

15. On information and belief, Defendants share common officers and directors and are agents of each other, or work in concert with each other with respect to the development, regulatory approval, marketing, sale, and distribution of pharmaceutical products throughout the United States, including in the State of New Jersey.

Answer: Paragraph 15 is directed to Actavis FL's relationship with entities that are no longer party to this litigation (Dkt. 18), and therefore no answer is necessary.

16. Defendants have previously submitted to the jurisdiction of the United States District Court for the District of New Jersey at least in *AstraZeneca AB, et al. v. Andrx Corporation, et al.*, No. 3:14-08030-JAP-TJB (D.N.J.); *AstraZeneca AB, et al. v. Actavis Laboratories FL, Inc., and Actavis Pharma, Inc.*, No. 3:14-07870-JAP-TJB (D.N.J.); *AstraZeneca AB, et al. v. Actavis Laboratories FL, Inc., and Actavis Pharma, Inc.*, No. 3:14-07263-MLC-TJB (D.N.J.); *Vivus Inc. et al. v. Actavis Laboratories FL, Inc. et al.*, No. 2:14-cv-03786-FSH-MAH (D.N.J.); *Supernus Pharmaceuticals, Inc. v. Actavis, Inc.*, et al., No. 13-04740-RMB-JS (D.N.J.); *Astrazeneca AB, et al. v. Watson Labs., Inc. – Florida, et al.*, No. 3:13-01669-JAP-TJB (D.N.J.).

Answer: Actavis FL does not contest personal jurisdiction in this Court for the limited purpose of this action only. Actavis FL admits that it has previously submitted to personal jurisdiction in this District for purposes of specific actions. Except as expressly admitted, Actavis FL denies the allegations of Paragraph 16.

17. On information and belief, Actavis FL, Andrx and Actavis Pharma operate as an integrated business ultimately owned and controlled by Actavis, Inc.

Answer: Paragraph 17 is directed to Actavis FL's relationship with entities that are no longer party to this litigation (Dkt. 18), and therefore no answer is necessary.

18. On information and belief, this Court has personal jurisdiction over Actavis FL by virtue of, *inter alia*: (1) its presence in New Jersey; (2) its course of conduct that is designed to cause the sale of its products in New Jersey; and (3) its purposeful availment of this forum previously for the purpose of litigating patent disputes.

Answer: Paragraph 18 contains conclusions of law for which no response is required. To the extent a response is required, and solely to conserve the resources of the parties and the Court, Actavis FL does not contest personal jurisdiction in this judicial district for the limited purpose of this action only. Actavis FL denies the remaining allegations of Paragraph 18.

19. On information and belief, this Court has personal jurisdiction over Actavis Pharma by virtue of, *inter alia*: (1) its presence in New Jersey; (2) its course of conduct that is designed to cause the sale of its products in New Jersey; and (3) its purposeful availment of this forum previously for the purpose of litigating patent disputes.

Answer: Paragraph 19 is directed to an entity that is no longer a party to this litigation (Dkt. 18), and therefore no answer is necessary.

20. On information and belief, this Court has personal jurisdiction over Andrx by virtue of, *inter alia*: (1) its course of conduct that is designed to cause the sale of its products in New Jersey; and (2) its purposeful availment of this forum previously for the purpose of litigating patent disputes.

Answer: Paragraph 20 is directed to an entity that is no longer a party to this litigation (Dkt. 18), and therefore no answer is necessary.

21. On information and belief, this Court has personal jurisdiction over Actavis, Inc. by virtue of, *inter alia*: (1) its presence in New Jersey; (2) its course of conduct that is designed to cause the sale of its products in New Jersey; (3) its wholesale drug and medical device license in New Jersey; and (4) its purposeful availment of this forum previously for the purpose of litigating patent disputes.

Answer: Paragraph 21 is directed to an entity that is no longer a party to this litigation (Dkt. 18), and therefore no answer is necessary.

FIRST CLAIM FOR RELIEF: '059 PATENT

22. Orexo realleges paragraphs 1-21 above as if set forth specifically here.

Answer: Actavis FL restates its answers to Paragraphs 1-21 as if fully set forth herein.

23. The '059 patent, (copy attached as Exhibit A), titled "Fentanyl Composition For The Treatment Of Acute Pain," was issued on July 6, 2004 to Diabact AB, upon assignment from the inventors Anders Pettersson, Christer Nyström, Hans Lennernäs, Bo Lennernäs and Thomas Hedner. Diabact AB changed its name to Orexo. The '059 patent claims, *inter alia*, a pharmaceutical composition for the treatment of acute pain by sublingual administration, and methods of treatment of a patient with such a composition.

Answer: Actavis FL admits that a purported copy of the '059 patent is attached to Orexo's complaint as Exhibit A and that, on its face, the '059 patent is entitled "Fentanyl Composition For The Treatment Of Acute Pain", bears an issuance date of July 6, 2004, identifies Anders Pettersson, Christer Nyström, Hans Lennernäs, Bo Lennernäs and Thomas Hedner as inventors, and indicates that Diabact AB is the assignee. Actavis FL admits that the claims of the '059 patent purport to cover, among other things, a certain pharmaceutical composition for the treatment of acute pain by sublingual administration, and methods of treatment of a patient with such a composition. Actavis FL is without sufficient knowledge and information to form a belief as to the remaining allegations of Paragraph 23 and therefore denies them.

24. Plaintiff Orexo has been and still is the owner of the '059 patent. The '059 patent will expire on September 24, 2019.

Answer: Paragraph 24 contains conclusions of law for which no response is required. To the extent a response is required, Actavis FL is without sufficient knowledge and

information to form a belief as to the allegations of Paragraph 24 and therefore denies them.

25. Defendant Actavis infringed one or more of the '059 patent claims under 35 U.S.C. § 271(e)(2) by filing its ANDA and seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in this patent prior to the expiration of the '059 patent.

Answer: Actavis FL admits that it submitted ANDA No. 207338 seeking FDA approval to manufacture and commercially market a product called "Fentanyl Sublingual tablets, CII" prior to the expiration of the '059 patent. Actavis FL denies the remaining allegations of Paragraph 25.

26. In the December 23 Notice Letter, Actavis FL notified Orexo that its ANDA contains a Paragraph IV certification of the type described in 21 U.S.C. § 355(j)(2)(A) with respect to the '059 patent. This statutory section requires, *inter alia*, certification by the ANDA applicant that the subject patent, here the '059 patent, "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . ." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)) specify, *inter alia*, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation."

Answer: Actavis FL admits that it sent a Notice Letter to Orexo on December 23, 2014 and that the Notice Letter notified Orexo that Actavis' ANDA contains a Paragraph IV certification of the type described in 21 U.S.C. § 355(j)(2)(A) with respect to the '059 patent. The remainder of Paragraph 26 is a recitation of various statutory and regulatory provisions, which provisions are the best evidence of their contents. Actavis FL denies any attempt by Orexo to characterize these statutory and regulatory provisions. Except as expressly admitted, Actavis FL denies the remaining allegations of Paragraph 26.

27. On information and belief, at the time the December 23 Notice Letter was served, Defendants were aware of the statutory provisions and regulations referred to in paragraph 26

above.

Answer: Actavis FL admits that it was aware of the statutory provisions and regulations referenced in Paragraph 26 at the time the December 23 Notice Letter was served. However, Actavis FL denies any attempt by Orexo to characterize those statutory and regulatory provisions, and specifically denies infringement of the '059 patent. Except as expressly admitted, Actavis FL denies the remaining allegations in Paragraph 27.

28. Defendants acknowledged and represented that the December 23 Notice Letter meets the statutory and regulatory requirements referred to in paragraph 26, above.

Answer: The December 23 Notice Letter described in Paragraph 28 is the best evidence of its contents, and Actavis FL denies any attempt by Orexo to characterize it. Actavis FL admits that the December 23 Notice Letter satisfied the requisite statutory and regulatory provisions. Except as expressly admitted, Actavis FL denies the remaining allegations in Paragraph 28.

29. In the December 23 Notice Letter, Actavis presented no invalidity or unenforceability positions relating to the '059 patent claims.

Answer: Actavis FL admits that in the December 23 Notice Letter, it did not provide a detailed statement of the invalidity or unenforceability of the '059 patent claims. Except as expressly admitted, Actavis FL denies the allegations of Paragraph 29.

30. The December 23 Notice Letter alleges that Actavis's ANDA Products do not infringe claims 1-20 of the '059 patent. Actavis refused Orexo's requests for information and samples that would permit investigation of Actavis's allegations of non-infringement. Accordingly, Orexo employs the judicial process to aid in discovery and to assess infringement of Actavis's ANDA Products. *See, e.g., Hoffman La-Roche v. Invamed*, 213 F.3d 1359 (Fed. Cir. 2000).

Answer: Actavis FL admits that the December 23 Notice Letter alleges that its ANDA Products do not infringe claims 1-20 of the '059 patent. Actavis FL denies the remaining allegations of Paragraph 30.

31. Unless enjoined by this Court, Actavis will directly infringe the '059 patent (either literally or under the doctrine of equivalents), upon receiving FDA approval, by making, using, offering to sell, importing, and/or selling Actavis's ANDA Products in the United States in violation of 35 U.S.C. § 271(a).

Answer: Actavis FL denies the allegations of Paragraph 31.

32. Unless enjoined by this Court, Actavis will induce the infringement of the '059 patent, upon receiving FDA approval, by actively and intentionally encouraging, aiding, and abetting the manufacture, offer for sale, sale, and use in the United States and/or import into the United States of Actavis's ANDA Products by others, including manufacturers, distributors, and/or consumers, with knowledge that such infringing acts are in contravention of Orexo's rights under the '059 patent and in violation of 35 U.S.C. § 271(b).

Answer: Actavis FL denies the allegations of Paragraph 32.

33. Unless enjoined by this Court, Actavis will induce the infringement of the '059 patent by actively and intentionally encouraging, through its label, the infringing use of Actavis's ANDA Products in the United States, by others, including distributors, prescribers, and/or consumers, in contravention of Orexo's rights under the '059 patent and in violation of 35 U.S.C. § 271(b).

Answer: Actavis FL denies the allegations of Paragraph 33.

34. Unless enjoined by this Court, Actavis will contribute to the infringement of the '059 patent by knowingly and intentionally selling materials and/or apparatuses, including chemical precursors of Actavis's ANDA Products or equipment for the manufacture of Actavis's ANDA Products to others, including manufacturers and distributors, where such materials and apparatuses are not staple articles or commodities of commerce suitable for non-infringing use, and are made or adapted especially for use in the manufacture, use, sale, or offer for sale of Actavis's ANDA Products in contravention of Orexo's rights under the '059 patent in violation of 35 U.S.C. § 271(c).

Answer: Actavis FL denies the allegations of Paragraph 34.

35. Orexo will be substantially and irreparably damaged and harmed if Actavis's infringement of the '059 patent is not enjoined.

Answer: Actavis FL denies the allegations of Paragraph 35.

36. Orexo does not have an adequate remedy at law for Actavis's infringement of the '059 patent.

Answer: Actavis FL denies the allegations of Paragraph 36.

37. This case is an exceptional one, and Orexo is entitled to an award of reasonable

attorney's fees under 35 U.S.C. § 285.

Answer: Actavis FL denies the allegations of Paragraph 37.

SECOND CLAIM FOR RELIEF: '910 PATENT

38. Orexo realleges paragraphs 1-37 above as if set forth specifically here.

Answer: Actavis FL restates its answers to Paragraphs 1-37 as if fully set forth herein.

39. The '910 patent, (copy attached as Exhibit B), titled "Pharmaceutical Composition For The Treatment Of Acute Disorders," was issued on July 13, 2004 to Diabact AB, upon assignment from the inventors Anders Pettersson and Christer Nyström. Diabact AB changed its name to Orexo. The '910 patent claims, *inter alia*, a pharmaceutical composition for the treatment of acute disorders by sublingual administration, and methods of treatment of a patient with such a composition.

Answer: Actavis FL admits that a purported copy of the '910 patent is attached to Orexo's complaint as Exhibit B and that, on its face, the '910 patent is entitled "Pharmaceutical Composition For The Treatment Of Acute Disorders", bears an issuance date of July 13, 2004, identifies Anders Pettersson and Christer Nyström as inventors, and indicates that Diabact AB is the assignee. Actavis FL admits that the claims of the '910 patent purport to cover, among other things, a certain pharmaceutical composition for the treatment of acute disorders by sublingual administration, and methods of treatment of a patient with such a composition. Actavis FL is without sufficient knowledge and information to form a belief as to the remaining allegations of Paragraph 39 and therefore denies them.

40. Plaintiff Orexo has been and still is the owner of the '910 patent. The '910 patent will expire on September 24, 2019.

Answer: Paragraph 40 contains conclusions of law for which no response is required. To the extent a response is required, Actavis FL is without sufficient knowledge and information to form a belief as to the allegations of Paragraph 40 and therefore denies them.

41. Defendant Actavis infringed one or more of the '910 patent claims under 35 U.S.C. § 271(e)(2) by filing its ANDA and seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in this patent prior to the expiration of the '910 patent.

Answer: Actavis FL admits that it submitted ANDA No. 207338 seeking FDA approval to manufacture and commercially market a product called "Fentanyl Sublingual tablets, CII" prior to the expiration of the '910 patent. Actavis FL denies the remaining allegations of Paragraph 41.

42. In the December 23 Notice Letter, Actavis FL notified Orexo that its ANDA contains a Paragraph IV certification of the type described in 21 U.S.C. § 355(j)(2)(A) with respect to the '910 patent. This statutory section requires, *inter alia*, certification by the ANDA applicant that the subject patent, here the '910 patent, "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . ." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)) specify, *inter alia*, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation."

Answer: Actavis FL admits that it sent a Notice Letter to Orexo on December 23, 2014 and that the Notice Letter notified Orexo that Actavis' ANDA contains a Paragraph IV certification of the type described in 21 U.S.C. § 355(j)(2)(A) with respect to the '910 patent. The remainder of Paragraph 42 is a recitation of various statutory and regulatory provisions, which provisions are the best evidence of their contents. Actavis FL denies any attempt by Orexo to characterize these statutory and regulatory provisions. Except as expressly admitted, Actavis FL denies the remaining allegations in Paragraph 42.

43. On information and belief, at the time the December 23 Notice Letter was served, Defendants were aware of the statutory provisions and regulations referred to in paragraph 42 above.

Answer: Actavis FL admits that it was aware of the statutory provisions and regulations referenced in Paragraph 42 at the time the December 23 Notice Letter was served. However, Actavis FL denies any attempt by Orexo to characterize those statutory and regulatory provisions, and specifically denies infringement of the '910 patent. Except as expressly admitted, Actavis FL denies the remaining allegations in Paragraph 43.

44. Defendants acknowledged and represented that the December 23 Notice Letter meets the statutory and regulatory requirements referred to in paragraph 42, above.

Answer: The December 23 Notice Letter described in Paragraph 44 is the best evidence of its contents, and Actavis FL denies any attempt by Orexo to characterize it. Actavis FL admits that the December 23 Notice Letter satisfied the requisite statutory and regulatory provisions. Except as expressly admitted, Actavis FL denies the remaining allegations in Paragraph 44.

45. In the December 23 Notice Letter, Actavis presented no invalidity or unenforceability positions relating to the '910 patent claims.

Answer: Actavis FL admits that in the December 23 Notice Letter, it did not provide a detailed statement of the invalidity or unenforceability of the '910 patent claims. Except as expressly admitted, Actavis FL denies the allegations of Paragraph 45.

46. The December 23 Notice Letter alleges that Actavis's ANDA Products do not infringe claims 1-21 of the '910 patent. Actavis refused Orexo's requests for information and samples that would permit investigation of Actavis's allegations of non-infringement. Accordingly, Orexo employs the judicial process to aid in discovery and to assess infringement of Actavis's ANDA Products. *See, e.g., Hoffman La-Roche v. Invamed*, 213 F.3d 1359 (Fed. Cir. 2000).

Answer: Actavis FL admits that the December 23 Notice Letter alleges that its ANDA Products do not infringe claims 1-21 of the '910 patent. Actavis FL denies the remaining allegations of Paragraph 46.

47. Unless enjoined by this Court, Actavis will directly infringe the '910 patent

(either literally or under the doctrine of equivalents), upon receiving FDA approval, by making, using, offering to sell, importing, and/or selling Actavis's ANDA Products in the United States in violation of 35 U.S.C. § 271(a).

Answer: Actavis FL denies the allegations of Paragraph 47.

48. Unless enjoined by this Court, Actavis will induce the infringement of the '910 patent, upon receiving FDA approval, by actively and intentionally encouraging, aiding, and abetting the manufacture, offer for sale, sale, and use in the United States and/or import into the United States of Actavis's ANDA Products by others, including manufacturers, distributors, and/or consumers, with knowledge that such infringing acts are in contravention of Orexo's rights under the '910 patent and in violation of 35 U.S.C. § 271(b).

Answer: Actavis FL denies the allegations of Paragraph 48.

49. Unless enjoined by this Court, Actavis will induce the infringement of the '910 patent by actively and intentionally encouraging, through its label, the infringing use of Actavis's ANDA Products in the United States, by others, including distributors, prescribers, and/or consumers, in contravention of Orexo's rights under the '910 patent and in violation of 35 U.S.C. § 271(b).

Answer: Actavis FL denies the allegations of Paragraph 49.

50. Unless enjoined by this Court, Actavis will contribute to the infringement of the '910 patent by knowingly and intentionally selling materials and/or apparatuses, including chemical precursors of Actavis's ANDA Products or equipment for the manufacture of Actavis's ANDA Products to others, including manufacturers and distributors, where such materials and apparatuses are not staple articles or commodities of commerce suitable for non-infringing use, and are made or adapted especially for use in the manufacture, use, sale, or offer for sale of Actavis's ANDA Products in contravention of Orexo's rights under the '910 patent in violation of 35 U.S.C. § 271(c).

Answer: Actavis FL denies the allegations of Paragraph 50.

51. Orexo will be substantially and irreparably damaged and harmed if Actavis's infringement of the '910 patent is not enjoined.

Answer: Actavis FL denies the allegations of Paragraph 51.

52. Orexo does not have an adequate remedy at law for Actavis's infringement of the '910 patent.

Answer: Actavis FL denies the allegations of Paragraph 52.

53. This case is an exceptional one, and Orexo is entitled to an award of reasonable attorney's fees under 35 U.S.C. § 285.

Answer: Actavis FL denies the allegations of Paragraph 53.

THIRD CLAIM FOR RELIEF: '132 PATENT

54. Orexo realleges paragraphs 1-53 above as if set forth specifically here.

Answer: Actavis FL restates its answers to Paragraphs 1-53 as if fully set forth herein.

55. The '132 patent, (copy attached as Exhibit C), titled "Pharmaceutical Composition For The Treatment Of Acute Disorders," was issued on March 22, 2011 to Orexo upon assignment from the inventors, Anders Pettersson, Christer Nyström, Hans Lennernäs, Bo Lennernäs, and Thomas Hedner. The '132 patent claims, *inter alia*, methods of treatment of breakthrough pain by sublingual administration of a pharmaceutical composition.

Answer: Actavis FL admits that a purported copy of the '132 patent is attached to Orexo's complaint as Exhibit C and that, on its face, the '132 patent is entitled "Pharmaceutical Composition For The Treatment Of Acute Disorders", bears an issuance date of March 22, 2011, identifies Anders Pettersson and Christer Nyström as inventors, and by way of a certificate of correction, further identifies Hans Lennernäs, Bo Lennernäs and Thomas Hedner as inventors, and indicates that Orexo AB is the assignee. Actavis FL admits that the claims of the '132 patent purport to cover, among other things, methods of treatment of breakthrough pain by sublingual administration of a certain pharmaceutical composition. Actavis FL is without sufficient knowledge and information to form a belief as to the remaining allegations of Paragraph 55 and therefore denies them.

56. Plaintiff Orexo has been and still is the owner of the '132 patent. The '132 patent will expire on September 24, 2019.

Answer: Paragraph 56 contains conclusions of law for which no response is required. To the extent a response is required, Actavis FL is without sufficient knowledge and information to form a belief as to the allegations of Paragraph 56 and therefore denies them.

57. Defendant Actavis infringed one or more of the '132 patent claims under 35

U.S.C. § 271(e)(2) by filing its ANDA and seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in this patent prior to the expiration of the '132 patent.

Answer: Actavis FL admits that it submitted ANDA No. 207338 seeking FDA approval to manufacture and commercially market a product called "Fentanyl Sublingual tablets, CII" prior to the expiration of the '132 patent. Actavis FL denies the remaining allegations of Paragraph 57.

58. In the December 23 Notice Letter, Actavis FL notified Orexo that its ANDA contains a Paragraph IV certification of the type described in 21 U.S.C. § 355(j)(2)(A) with respect to the '132 patent. This statutory section requires, *inter alia*, certification by the ANDA applicant that the subject patent, here the '132 patent, "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . ." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)) specify, *inter alia*, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation."

Answer: Actavis FL admits that it sent a Notice Letter to Orexo on December 23, 2014 and that the Notice Letter notified Orexo that Actavis' ANDA contains a Paragraph IV certification of the type described in 21 U.S.C. § 355(j)(2)(A) with respect to the '132 patent. The remainder of Paragraph 58 is a recitation of various statutory and regulatory provisions, which provisions are the best evidence of their contents. Actavis FL denies any attempt by Orexo to characterize these statutory and regulatory provisions. Except as expressly admitted, Actavis FL denies the remaining allegations in Paragraph 58.

59. On information and belief, at the time the December 23 Notice Letter was served, Defendants were aware of the statutory provisions and regulations referred to in paragraph 58 above.

Answer: Actavis FL admits that it was aware of the statutory provisions and

regulations referenced in Paragraph 58 at the time the December 23 Notice Letter was served. However, Actavis FL denies any attempt by Orexo to characterize those statutory and regulatory provisions, and specifically denies infringement of the '132 patent. Except as expressly admitted, Actavis FL denies the remaining allegations in Paragraph 59.

60. Defendants acknowledged and represented that the December 23 Notice Letter meets the statutory and regulatory requirements referred to in paragraph 58, above.

Answer: The December 23 Notice Letter described in Paragraph 60 is the best evidence of its contents, and Actavis FL denies any attempt by Orexo to characterize it. Actavis FL admits that the December 23 Notice Letter satisfied the requisite statutory and regulatory provisions. Except as expressly admitted, Actavis FL denies the remaining allegations in Paragraph 60.

61. In the December 23 Notice Letter, Actavis presented no invalidity or unenforceability positions relating to the '132 patent claims.

Answer: Actavis FL admits that in the December 23 Notice Letter, it did not provide a detailed statement of the invalidity or unenforceability of the '132 patent claims. Except as expressly admitted, Actavis FL denies the allegations of Paragraph 61.

62. The December 23 Notice Letter alleges that Actavis's ANDA Products do not infringe claims 1-11 of the '132 patent. Actavis refused Orexo's requests for information and samples that would permit investigation of Actavis's allegations of non-infringement. Accordingly, Orexo employs the judicial process to aid in discovery and to assess infringement of Actavis's ANDA Products. *See, e.g.*, *Hoffman La-Roche v. Invamed*, 213 F.3d 1359 (Fed. Cir. 2000).

Answer: Actavis FL admits that the December 23 Notice Letter alleges that its ANDA Products do not infringe claims 1-11 of the '132 patent. Actavis FL denies the remaining allegations of Paragraph 62.

63. Unless enjoined by this Court, Actavis will directly infringe the '132 patent (either literally or under the doctrine of equivalents), upon receiving FDA approval, by making, using, offering to sell, importing, and/or selling Actavis's ANDA Products in the United States

in violation of 35 U.S.C. § 271(a).

Answer: Actavis FL denies the allegations of Paragraph 63.

64. Unless enjoined by this Court, Actavis will induce the infringement of the '132 patent, upon receiving FDA approval, by actively and intentionally encouraging, aiding, and abetting the manufacture, offer for sale, sale, and use in the United States and/or import into the United States of Actavis's ANDA Products by others, including manufacturers, distributors, and/or consumers, with knowledge that such infringing acts are in contravention of Orexo's rights under the '132 patent and in violation of 35 U.S.C. § 271(b).

Answer: Actavis FL denies the allegations of Paragraph 64.

65. Unless enjoined by this Court, Actavis will induce the infringement of the '132 patent by actively and intentionally encouraging, through its label, the infringing use of Actavis's ANDA Products in the United States, by others, including distributors, prescribers, and/or consumers, in contravention of Orexo's rights under the '132 patent and in violation of 35 U.S.C. § 271(b).

Answer: Actavis FL denies the allegations of Paragraph 65.

66. Unless enjoined by this Court, Actavis will contribute to the infringement of the '132 patent by knowingly and intentionally selling materials and/or apparatuses, including chemical precursors of Actavis's ANDA Products or equipment for the manufacture of Actavis's ANDA Products to others, including manufacturers and distributors, where such materials and apparatuses are not staple articles or commodities of commerce suitable for non-infringing use, and are made or adapted especially for use in the manufacture, use, sale, or offer for sale of Actavis's ANDA Products in contravention of Orexo's rights under the '132 patent in violation of 35 U.S.C. § 271(c).

Answer: Actavis FL denies the allegations of Paragraph 66.

67. Orexo will be substantially and irreparably damaged and harmed if Actavis's infringement of the '132 patent is not enjoined.

Answer: Actavis FL denies the allegations of Paragraph 67.

68. Orexo does not have an adequate remedy at law for Actavis's infringement of the '132 patent.

Answer: Actavis FL denies the allegations of Paragraph 68.

69. This case is an exceptional one, and Orexo is entitled to an award of reasonable attorney's fees under 35 U.S.C. § 285.

Answer: Actavis FL denies the allegations of Paragraph 69.

PRAYER FOR RELIEF

The remainder of Orexo's Complaint recites a prayer for relief to which no response is required. To the extent any response is required, Actavis FL denies that Orexo is entitled to any remedy or relief.

AFFIRMATIVE DEFENSES

Actavis FL hereby asserts the following defenses without undertaking or otherwise shifting any applicable burdens of proof. Actavis FL reserves the right to assert additional defenses, as warranted by facts learned through investigation and discovery.

FIRST AFFIRMATIVE DEFENSE

Actavis FL's proposed generic product that is the subject of ANDA No. 207338 does not infringe, has not infringed, and would not, if marketed, infringe any valid and enforceable claim of U.S. Patent Nos. 6,759,059, 6,761,910, or 7,910,132 (collectively, "the Patents-in-Suit") either directly or indirectly, and either literally or under the doctrine of equivalents.

SECOND AFFIRMATIVE DEFENSE

Plaintiff's Complaint fails to state a claim upon which relief may be granted.

THIRD AFFIRMATIVE DEFENSE

Any additional defenses that discovery may reveal.

WHEREFORE, Defendant Actavis Laboratories FL, Inc. hereby demands judgment dismissing Plaintiff's Complaint with prejudice, for costs of suit, and for such other relief as the Court may deem just.

COUNTERCLAIMS

Defendant and Counterclaim–Plaintiff Actavis Laboratories FL, Inc. ("Actavis FL"), by way of counterclaim against Plaintiff–Counterclaim Defendant Orexo AB ("Orexo") states as

follows:

Jurisdiction and Venue

1. This Court has subject matter jurisdiction over these Counterclaims pursuant to 28 U.S.C. §§ 1331, 1338, 2201, and 2202. Orexo has sued Actavis FL in the present action, alleging infringement of U.S. Patent Nos. 6,759,059 ("the '059 patent"), 6,761,910 ("the '910 patent"), and 7,910,132 ("the '132 patent") (collectively, "the Patents-in-Suit").

2. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

Parties

3. Actavis Laboratories FL, Inc. is a corporation organized and existing under the laws of the State of Florida, having its principal place of business at 4955 Orange Drive, Davie, Florida 33314.

4. Orexo AB is a company organized and existing under the laws of Sweden, having its principal place of business in Uppsala, Sweden. Orexo AB was formerly known as Diabact AB.

Factual Background

A. FDA Approval Of New Brand Name Drugs

5. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Hatch-Waxman Amendments, sets forth the rules that the Food and Drug Administration ("FDA") follows when considering whether to approve the marketing of both brand-name and generic drugs.

6. Under the FFDCA, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by the FDA. *See* 21 U.S.C. § 355.

7. An NDA must include, among other things, the number of any patent that

allegedly claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1), -(c)(2); 21 C.F.R. § 314.53(b)(1), -(c)(2).

8. Upon approval of the NDA, the FDA publishes patent information for the approved drug in "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 C.F.R. § 314.53(e).

9. The FDA's duties with respect to Orange Book listings are purely ministerial. If the NDA-holder submits a patent to the FDA for listing in the Orange Book, the patent is listed in the Orange Book. *See* 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53(e)-(f). The FDA does not substantively review the submitted patent information to ensure that it is accurate or that the NDA holder properly submitted it in connection with the NDA drug (or "reference listed drug"), but instead relies on the NDA holder to properly list the patents.

B. FDA Approval Of New Generic Drugs

10. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments, to the FFDCA. *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e)). Congress passed the Hatch-Waxman Amendments, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition.

11. Under the Hatch-Waxman Amendments, a generic manufacturer submits to the FDA what is called an Abbreviated New Drug Application ("ANDA").

12. Among other things, an ANDA must also contain a "certification" as to each patent that the NDA holder has submitted to the FDA for listing in the Orange Book in connection with the reference listed drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R.

§ 314.94(a)(12).

13. A "Paragraph IV" certification asserts that the listed patent is invalid, unenforceable, and/or will not be infringed and, on that basis, the applicant seeks FDA approval of the generic product prior to patent expiration. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); *see also* 21 C.F.R. § 314.94(a)(12)(i)(A)(4).

14. An applicant submitting an ANDA containing a Paragraph IV certification must notify both the patent holder and NDA holder of each of its Paragraph IV certifications. *See* 21 U.S.C. § 355(j)(2)(B).

15. Upon receiving notice of the Paragraph IV certifications, the patent holder has 45 days in which to file an infringement suit against the generic manufacturer. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. § 271(e)(5).

16. Patent holders have a significant strategic incentive to file suit within 45 days of receiving notice of the Paragraph IV certifications because doing so, regardless of merit, automatically prevents the FDA from approving the generic maker's ANDA for a period of 30 months, absent certain exceptions. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

17. If the court hearing the infringement action decides the patent is valid, enforceable, and would be infringed by the product proposed in the ANDA, the FDA will not approve the ANDA until the patent expires. *Id.* If, however, the court hearing the infringement action rules before the expiration of the 30-month period that the patent is invalid, unenforceable, or not infringed, "including any substantive determination that there is no cause of action for patent infringement or invalidity," the FDA may approve the ANDA effective on the date when the court enters the judgment. *Id.*

C. Actavis FL's ANDA

18. Actavis FL filed ANDA No. 207338 seeking approval for a tablet containing fentanyl citrate as its active pharmaceutical ingredient ("Actavis FL's ANDA product").

19. On information and belief, the FDA lists Galena Biopharma, Inc. as the holder of New Drug Application ("NDA") No. 022510 for Abstral® (fentanyl) sublingual tablets CII.

20. On information and belief, the USPTO identifies Diabact AB as the assignee of the '059 and '910 patents, and Orexo AB as the assignee of the '132 patent. Orexo AB alleges that Diabact AB changed its name to Orexo AB.

21. On information and belief, NDA No. 022510 is directed to Abstral® (Fentanyl) Sublingual tablets CII.

22. On information and belief, Orexo lists the Patents-in-Suit in the Orange Book in connection with NDA No. 022510.

23. Actavis FL's ANDA includes a Paragraph IV certification with respect to the Patents-in-Suit.

24. Orexo initiated the present litigation by filing a complaint against Actavis FL on February 4, 2015.

25. Orexo has alleged in the present action that Actavis FL has infringed and will directly and indirectly infringe the Patents-in-Suit by filing ANDA No. 207338 with the FDA and by making, using, offering to sell, importing and/or selling the products described in that ANDA.

26. As a consequence, there is an actual and justiciable controversy between Actavis FL and Orexo as to whether the claims of the Patents-in-Suit are being infringed or will be infringed by the submission of Actavis FL's ANDA No. 207338 or by the making, using,

offering to sell, importing and/or selling of the products described therein.

Count I
Declaration of Noninfringement of the '059 Patent

27. Actavis FL restates and incorporates the allegations of Paragraphs 1-26 as if fully set forth herein.

28. Orexo alleges ownership of the '059 patent and has brought claims against Actavis FL alleging infringement of the '059 patent.

29. The manufacture, use, offer to sell, importation, or sale of Actavis FL's ANDA products do not and would not infringe any valid or enforceable claim of the '059 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

30. A present, genuine, and justiciable controversy exists between Actavis FL and Orexo regarding, *inter alia*, the issue of whether the manufacture, use, offer to sell, importation, or sale of Actavis FL's ANDA products would infringe any valid or enforceable claim of the '059 patent.

31. Actavis FL is entitled to a declaration that the manufacture, use, offer to sell, importation, or sale of Actavis FL's ANDA products would not infringe any valid or enforceable claim of the '059 patent.

Count II
Declaration of Noninfringement of the '910 Patent

32. Actavis FL restates and incorporates the allegations of Paragraphs 1-31 as if fully set forth herein.

33. Orexo alleges ownership of the '910 patent and has brought claims against Actavis FL alleging infringement of the '910 patent.

34. The manufacture, use, offer to sell, importation, or sale of Actavis FL's ANDA

products do not and would not infringe any valid or enforceable claim of the '910 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

35. A present, genuine, and justiciable controversy exists between Actavis FL and Orexo regarding, *inter alia*, the issue of whether the manufacture, use, offer to sell, importation, or sale of Actavis FL's ANDA products would infringe any valid or enforceable claim of the '910 patent.

36. Actavis FL is entitled to a declaration that the manufacture, use, offer to sell, importation, or sale of Actavis FL's ANDA products would not infringe any valid or enforceable claim of the '910 patent.

Count III
Declaration of Noninfringement of the '132 Patent

37. Actavis FL restates and incorporates the allegations of Paragraphs 1-36 as if fully set forth herein.

38. Orexo alleges ownership of the '132 patent and has brought claims against Actavis FL alleging infringement of the '132 patent.

39. The manufacture, use, offer to sell, importation, or sale of Actavis FL's ANDA products do not and would not infringe any valid or enforceable claim of the '132 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

40. A present, genuine, and justiciable controversy exists between Actavis FL and Orexo regarding, *inter alia*, the issue of whether the manufacture, use, offer to sell, importation, or sale of Actavis FL's ANDA products would infringe any valid or enforceable claim of the '132 patent.

41. Actavis FL is entitled to a declaration that the manufacture, use, offer to sell, importation, or sale of Actavis FL's ANDA products would not infringe any valid or enforceable

claim of the '132 patent.

REQUEST FOR RELIEF

WHEREFORE, Defendant–Counterclaim Plaintiff Actavis Laboratories FL, Inc. respectfully requests that this Court enter a Judgment and Order in its favor and against Plaintiff–Counterclaim Defendant Orexo AB as follows:

(a) declaring that Actavis FL has not infringed and would not infringe any valid and enforceable claim of U.S. Patent No. 6,759,059;

(b) declaring that Actavis FL has not infringed and would not infringe any valid and enforceable claim of U.S. Patent No. 6,761,910;

(c) declaring that Actavis FL has not infringed and would not infringe any valid and enforceable claim of U.S. Patent No. 7,910,132;

(d) declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Actavis FL its attorneys' fees, costs, and expenses in this action; and

(e) awarding Actavis FL any further and additional relief as the Court deems just and proper.

JURY DEMAND

Defendant Actavis Laboratories FL, Inc. demands trial by jury as to all issues so triable.

Dated: March 26, 2015

CONNELL FOLEY LLP

/s/ Liza M. Walsh

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 AND 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, the undersigned counsel for Defendant Actavis Laboratories FL, Inc. certifies that, to the best of her knowledge, information, and belief, the matter in controversy is not the subject of any other action or proceeding.

Dated: March 26, 2015

CONNELL FOLEY LLP

/s/ Liza M. Walsh
Liza M. Walsh

CERTIFICATION PURSUANT TO L. CIV. R. 201.1

Pursuant to Local Civil Rule 201.1, the undersigned counsel for Defendant Actavis Laboratories FL, Inc. certifies that, to the best of her knowledge, information, and belief, the above captioned matter is not subject to compulsory arbitration in that the Plaintiff seeks, *inter alia*, injunctive relief.

Dated: March 26, 2015

CONNELL FOLEY LLP

/s/ Liza M. Walsh
Liza M. Walsh

CERTIFICATE OF SERVICE

I hereby certify that on March 26, 2015, the foregoing ANSWER, AFFIRMATIVE DEFENSES, COUNTERCLAIMS, AND JURY DEMAND OF DEFENDANT ACTAVIS LABORATORIES FL, INC. was filed via CM/ECF with the Clerk of the Court and was thereby served on all counsel of record in this matter.

Dated: March 26, 2015

CONNELL FOLEY LLP

/s/ Liza M. Walsh
Liza M. Walsh